

REMARKS

Claims 1-16 are currently pending in the application. Claim 1 is the only claim in independent form. Claims 1, 3, 4, and 16 are amended solely to clarify the subject matter in the claims and remove unnecessary language that does not change the scope of the claims. No new matter has been added.

Claims 1 and 3-6 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,011,996 to Gielen, et al. in view of U.S. Patent No. 6,413,263 to Lobdill, et al. The Office Action states that Gielen, et al. teaches a stereoguide comprising first and second guide elements 44 spaced relative to each other through which instruments are passed along an axis of insertion towards a target; characterized by a first clamp 42 attached to the guide member 16 having a clamping position on the axis between the guide elements and the target, or on the opposite side of the guide elements for clamping instruments passing through the guide elements. The Office Action holds that Gielen, et al. fails to teach a second clamp carried by a leg extending from the second guide and clamps between the guide elements and the target or wherein each clamp is swivelable away from its clamping position. The Office Action holds that Lobdill teaches a stereotactic guide wherein swivelable clamp 18 is carried by a leg extending from the guide and clamps between guide element 50 and target 48 in order to grip the instrument near the target. Therefore, the Office Action holds that it would have been obvious to one of skill in the art to modify the device of Gielen, et al. with a clamp carried by a leg extending from the second guide and clamps between guide elements and the target as taught by Lobdill in order to grip the instrument near the target. Reconsideration of the rejection of the claims under 35 U.S.C. §103(a) is respectfully requested.

More specifically, Gielen, et al. discloses a brain lead 30 held in position by a stereotactic instrument including a lead holder assembly 41 supporting a lead holder 42. The lead 30 includes electrodes. A micro-positioner 45 is used to advance the lead one cell at a time in order to make recordings of cells. The lead holder 42 is not a

clamp as contended by the Office Action. If it were a clamp, during use of the lead, the lead holder would be required to be clamped and unclamped and moved out of position as the lead is advanced through the cells. However, this is not the process disclosed by Gielen, et al. Rather, the lead is positioned for a trajectory and advanced by the micro-positioner from one cell to the next so that recordings can be made (col. 4, lines 36-57). No securing action is performed with the lead holder. The lead holder is merely a place for the lead to *rest* and move through as the lead is advanced. A clamp according to the present invention takes on the common dictionary meaning, i.e. a device for fastening or securing (see p. 5, line 7 – “preventing longitudinal movement of the instrument”). Therefore, Gielen, et al. does not disclose one clamp, let alone two, as are required by the presently pending claims. Furthermore, there is no suggestion or motivation in Gielen, et al. to include a clamp. The process of recording from cells and stimulation of cells requires that the lead be accessible and readily able to move from one cell to the next. The micro-positioner of Gielen, et al. must be able to freely adjust the position of the lead, and this cannot happen if time must be spent clamping and unclamping the lead.

The Lobdill, et al. patent specifically discloses a single microdrive unit 46 and a single swiveling clamping member 18. It is black letter law that there must be some suggestion in the prior art for their combination to derive a claimed invention. The Lobdill, et al. patent, in a contrary manner, teaches away from any suggestion (keeping in mind that the suggestion should be in the primary reference, the Gielen, et al. patent, which undisputedly is not found therein). The Lobdill, et al. patent specifically states, in column 2, lines 39 et seq., that “attempting to hold the probe at a point at or above the arch of the stereotactic frame allows for movement of the probe within the brain of the patient. In addition, the stereotactic apparatus is typically partially disassembled to expedite the anchoring procedure. Such disassembly can introduce mechanical displacement, disturbing the probe and moving it from its desired location. Incorrect placement of a probe reduces the degree of, or entirely prevents, the success of the surgical procedure. Accordingly, there is a need in the art for devices and methods that maintain the correct position of the probe during anchoring of the probe

in the patient and during partial disassembly of the stereotactic apparatus." In other words, if one was to follow the teaching of the Lobdill, et al. patent, one would not use any clamping above the probes and would only use a clamp between the guide or microdrive and the target. The Lobdill, et al. patent requires this to allow for disassembly of the stereotactic apparatus for insertion of the probe. In contradistinction, the present invention does not require any disassembly of the stereotactic apparatus to allow for the probe insertions, as detailed and on page 11, lines 15, et seq., and as discussed above.

Amended independent claim 1 claims a stereoguide including first and second guide elements spaced relative to each other and first and second clamps, the first clamp having a clamping position on the axis between the guide elements and the target and a second clamp having a clamping position on the axis of insertion and on the opposite side of the guide elements of the first clamp. This combination of clamps and guides allows for performance of the specific methods, as described in detail beginning on page 11, line 15, et seq. As specifically stated therein, the specific combination of guides and clamps and their positioning provide the particular advantage that, on the first pass, the guide wire being stiffened by the tube 20 hits the target and then by inserting a guide tube short of the target, the brain target is fixed and the guide tube facilitates the insertion of a very fine instrument to the target. The combination of insertion of the various tubes and elements, and the stiffening of the guide wire by the positioning of the specific positioning of the clamps, cannot at all be obtained by the prior art. Likewise, the device in independent claim 1 does not have to be assembled and disassembled to perform the disclosed method.

Hence, even if one were to combine the teachings of the Gielen, et al. and Lobdill, et al. patents as required by the disclosures in each patent, one would either not have any clamps, as required by the Gielen, et al. patent, or one would derive a stereotactic apparatus including a single clamp between a microdrive and the target as required by the Lobdill, et al. patent and (1) abandon any further clamping and (2) have an assembly that requires disassembly for the insertion of the probe. In other words,

taking the teachings of the prior art as specifically stated therein, even a combination of the prior art references cannot be used to derive the present invention. It is further black letter law that one cannot ignore the teaching of the prior art references in order to combine them to derive an invention. This can only be done through hindsight after first understanding the present invention while ignoring specific requirements of the prior art. The Office Action is essentially using hindsight to read elements into the prior art which simply do not exist. Hence, it is respectfully submitted that the presently pending independent claim is patentable over the cited prior art.

Claims 7, 8, and 16 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,011,996 to Gielen, et al. in view of U.S. Patent No. 6,413,263 to Lobdill, et al., and further in view of U.S. Patent No. 4,504,269 to Durand. The Office Action states that the combination of Gielen, et al. and Lobdill, et al. teaches a stereoguide comprising all the limitations of preceding dependent claim 1 as previously described, but fails to teach the method as claimed. However, the Office Action asserts that the method described in the application is a well known tube introduction method known as the "Seldinger Technique" described in the "Acta Radiologica" journal in 1953 and utilized in Durand. According to this well-known method for introducing a tubular member into the body and as illustrated by Durand, a needle is inserted into the body, a wire is inserted through the needle, and the needle is then removed. The tube is then threaded into the body by being guided by the wire over which it is moving. The wire is then removed from the tube. This method is utilized in order to provide a less traumatic entry. Therefore, the Office Action holds that it would have been obvious to one of skill in the art to perform the "Seldinger Technique" of insertion for the instrument holding cannula with the combination of Gielen, et al. and Lobdill, et al. as taught by Durand in order to provide a less traumatic entry for the cannula. The Office Action further holds that the combination of Gielen, et al., Lobdill, et al. and Durand further teaches wherein the insertion of wire into the support tube results in the wire projecting from the end of the support tube (it is noted that in order to remove the insertion wire as required by Durand, the wire must be

longer than the support tube). Reconsideration of the rejection of the claims under 35 U.S.C. §103(a) is respectfully requested.

As stated above, the combination of Gielen, et al. and Lobdill, et al. do not disclose or suggest a stereoguide including first and second guide elements spaced relative to each other and first and second clamps, the first clamp having a clamping position on the axis between the guide elements and the target and a second clamp having a clamping position on the axis of insertion and on the opposite side of the guide elements of the first clamp as required by the currently pending independent claims. The use of this stereoguide in the methods of currently pending claims 7, 8, and 16 then can certainly not be disclosed or suggested by the further combination of Durand with Gielen, et al. and Lobdill, et al. Hence, it is respectfully submitted that the presently pending claims 7, 8, and 16 are patentable over the cited prior art.

Claim 9 stands rejected under 35 U.S.C. §103(a) as being unpatentable over the combination of Gielen, et al., Lobdill, et al., and Durand and further as a matter of design choice. The Office Action holds that the combination of Gielen, et al., Lobdill, et al., and Durand teaches all of the limitations of preceding dependent claims 1, 7, and 8 as previously described, but fails to disclose wherein the wire projects from the support tube towards the target by about 22 mm. The Office Action holds that since the Applicant has not disclosed that the wire projecting about 25 mm from the support tube solves any particular problem or provides any advantage over a system wherein the length of wire projecting past the support tube is not disclosed, it would have been an obvious matter of design choice to provide the wire about 25 mm past the support tube, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum range involves only routine skill in the art.

The combination of Gielen, et al., Lobdill, et al., and Durand do not disclose or suggest a stereoguide including first and second guide elements spaced relative to each other and first and second clamps, the first clamp having a clamping position on the axis between the guide elements and the target and a second clamp having a

clamping position on the axis of insertion and on the opposite side of the guide elements of the first clamp, nor the method of using the stereoguide as required by the currently pending independent claims. Using a certain wire length with the claimed stereoguide can certainly not be disclosed or suggested by the further combination of Gielen, et al., Lobdill, et al., Durand, and design choice. Hence, it is respectfully submitted that the presently pending claim 9 is patentable over the cited prior art.

The remaining dependent claims are all ultimately dependent upon the independent claim discussed above. No prior art reference makes up for the deficiencies of that reference as no prior art reference teaches the claim combination of features that derive a novel result of the present invention. Such a combination, as discussed above, cannot derive the present invention without hindsight after first understanding the present invention and then applying it to the prior art.

It is respectfully submitted that the present amendment places the application in condition for allowance as it removes all remaining issues in dispute. Specifically, the amendment removes all unnecessary language and clarifies the claims. The claims have been made no broader in scope thereby requiring no further searching and raising no new issues. In fact, all claims now include limitations of previously pending claims and were therefore previously searched. It is respectfully submitted that all of the claims are in condition for allowance.

In view of the above, it is respectfully submitted that the application is now in condition for allowance, which allowance is respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

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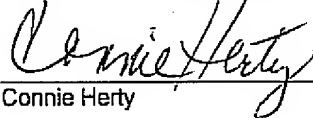
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